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10/527,672

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Rino Rappuoli

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NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

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1645

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/527,672 | Applicant(s) RAPPUOLI ET AL. | |
| | Examiner S. Devi, Ph.D. | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2,5,6,16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-15 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>070709</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 11/04/09 and 07/06/09 in response to the non-final office Action mailed 03/03/09. It is noted that the status identifier for claims 5 and 6 is incorrect since these claims are currently withdrawn. Applicants should provide the correct status identifiers in response to this Office Action.

Status of Claims

2) Claims 1-6, 8, 9 and 17-19 have been amended via the amendment filed 07/06/09. Claims 1-23 are pending.

The amended claim 2 now encompasses a non-elected GBS serotype species and therefore is withdrawn from consideration as being directed to a non-elected invention and/or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1, 3, 4, 7-15 and 18-23 are under examination.

Information Disclosure Statement

3) Acknowledgment is made of Applicants' Information Disclosure Statement filed 07/07/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 7(a) of the Office Action mailed 03/03/09 is withdrawn in light of Applicants' amendment to the specification.

7) The objection to the specification made in paragraph 7(b) of the Office Action mailed 03/03/09 is withdrawn in light of Applicants' amendment to the specification.

8) The objection to claims 1, 3, 4, 8, 9 and 18 made in paragraph 16 of the Office Action mailed 03/03/09 is maintained for the reason set forth therein.

Rejection(s) Withdrawn

9) The rejection of claim 1 and the claims dependent therefrom made in paragraph 9 of the Office Action mailed 03/03/09 under 35 U.S.C § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendment to the base claim.

10) The rejection of claims 1-4, 7-10, 18 and 19 made in paragraph 11(a) of the Office Action mailed 03/03/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

11) The rejection of claim 2 and the claims dependent therefrom made in paragraph 11(b) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim or the withdrawal of the claim from examination.

12) The rejection of claim 1 made in paragraphs 11(c), 11(d) and 11(h) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claims 1, 3, 4, 8 and 9 made in paragraph 11(e) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claims 1 and 4 made in paragraph 11(f) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

15) The rejection of claims 2 and 3 made in paragraph 11(g) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the withdrawal of the claim from examination.

16) The rejection of claim 19 made in paragraph 11(i) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claims 1, 2 and 3 made in paragraph 11(j) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims or the withdrawal of the claim from examination.

18) The rejection of claim 4 made in paragraph 11(k) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 18 made in paragraph 11(n) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 2-4, 7-12 and 18-23 made in paragraph 11(o) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim or the withdrawal of the claim from examination.

21) The rejection of claims 1-4 and 10-13 made in paragraph 13 of the Office Action mailed 03/03/09 under 35 U.S.C § 102(b) as being anticipated by Paoletti *et al.* (*Infect. Immun.* 62: 3236-3243, 1994), is withdrawn in light of Applicants' amendment to the claims and/or the base claim or the withdrawal of the claim from examination.

22) The rejection of claim 2 made in paragraph 15 of the Office Action mailed 03/03/09 under 35 U.S.C § 103(a) as being unpatentable over CHIRON S.P.A (WO 02/34771 A2, of record) ('771) in view of Wessels *et al.* (*Infect. Immun.* 61: 4760-4766, 1993, of record), is withdrawn. Claim 2, as amended, is now directed to a non-elected species.

23) The rejection of claim 4 made in paragraph 15 of the Office Action mailed 03/03/09 under 35 U.S.C § 103(a) as being unpatentable over CHIRON S.P.A (WO 02/34771 A2, of record) ('771) in view of Wessels *et al.* (*Infect. Immun.* 61: 4760-4766, 1993, of record), is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

24) The rejection of claim 18 made in paragraph 11(e) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for the reasons set forth therein. Claim 18 continues to include the limitation ‘as represented by’. See line 3.

25) The rejection of claim 10 made in paragraph 11(l) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for the reasons set forth therein.

Applicants submit that claim 10 is amended. However, claim 10 has not been amended. It is suggested that Applicants replace the above-identified limitation with the limitation --at least one of the at least two isolated GBS polypeptide antigens--.

26) The rejection of claim 12 made in paragraph 11(m) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein. Although Applicants claim that the spelling errors have been corrected, no such correction is apparent.

27) The rejection of claims 13-15 made in paragraph 11(o) of the Office Action mailed 03/03/09 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

28) The rejection of claims 1, 3, 7, 10-15 and 18-23 made in paragraph 15 of the Office Action mailed 03/03/09 under 35 U.S.C § 103(a) as being unpatentable over CHIRON S.P.A (WO 02/34771 A2, of record) (‘771) in view of Wessels *et al.* (*Infect. Immun.* 61: 4760-4766, 1993, of record), is maintained for the reason set forth therein and herein below.

Applicants cite the statute of 35 U.S.C § 103(a), the *Graham-Deere* factors, and MPEP § 2142, and contend that the Office bears the initial burden of establishing a *prima facie* case of obviousness. Applicants state that the cited portions of WO 02/34771 do not disclose the claimed composition. Applicants submit that claim 28 of WO 02/34771 is directed to a composition comprising ‘two’ or more, wherein each protein is a protein according to claim 1, 2 or 3, each of which recites almost 5,500 proteins. Applicants opine that this is not a disclosure of any of pairs of antigens specified in pending claims 1-4, 10-15 and 18-23. Applicants point to lines 9-10 of page 9 of WO 02/34771 and state that there is no disclosure of any of the antigens

recited in the pending claims. Applicants submit that pages 7 and 8 of WO 02/34771 do not describe any compositions comprising the specified GBS antigens. Applicants acknowledge that GBS 80 with its sequence identifier is listed on page 2992 of WO 02/34771 together with 117 other GBS proteins. Applicants acknowledge that GBS 322 with its sequence identifier is listed on page 2997 of WO 02/34771 together with 55 other GBS proteins. Applicants contend that Table IV lists many hundreds of GBS proteins and that there is no suggestion in Table IV to make any particular combination of the listed antigens. Applicants conclude that neither the cited portions nor any other part of WO 02/34771 provide a teaching or suggestion of a composition comprising the combinations of antigens recited in the pending claims. Applicants cite case law and state that obviousness requires at least a suggestion of all of the features in a claim and that rejections on obviousness cannot be sustained by mere conclusory statements, but there must be some articulated reasons with some rational underpinning to support the legal conclusion of obviousness. Applicants state that exemplary rationales that may support a conclusion of obviousness include choosing from a finite number of identified predictable solutions with a reasonable expectation of success. Applicants state that over 15,000,000 pairs of GBS antigens are possible from the GBS antigens disclosed in WO 02/34771 and that this is not "a finite number of identified, predictable solutions" which might support a *prima facie* case that any of claims 1-4, 10-15, and 18-23 are obvious. Applicants further state that even if, *arguendo*, one of ordinary skill in the art would have combined the teachings of WO 02/34771 and Wessels, the Office Action does not articulate a reason why any teachings in WO 02/34771 would have motivated one of ordinary skill in the art to select any of the particular combinations of GBS antigens recited in the pending claims. Applicants allege that the Office has not made a *prima facie* case of obviousness.

Applicants' arguments have been carefully considered, but are not persuasive.

First, the instant claims include the open claim language 'comprising'. The transitional limitation 'comprising' represents open-ended claim language and therefore, does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts').

Therefore, the limitation ‘comprising’ in the instant claim(s) allows any number of isolated GBS polypeptides to be present in the claimed composition. Second, the limitation ‘at least one GBS polypeptide antigens’ in claim 1, for example, places no upper limit to the number of GBS polypeptide antigens that can be present in the claimed composition along with GBS 80 and GBS 322 proteins having SEQ ID NO: 8780 (i.e., the instantly recited SEQ ID NO: 2) and SEQ ID NO: 8540 (i.e., the instantly recited SEQ ID NO: 322). Clearly, WO 02/34771 is properly applied in the 35 U.S.C § 103(a) rejection and no reasoning as to why WO 02/34771 would have motivated one of ordinary skill in the art to select any of the particular combinations of GBS antigens is warranted since the composition of WO 02/34771 already contains the two recited polypeptides. Contrary to Applicants’ assertion, while pages 7 and 8 of WO 02/34771 describe the presence of more than one GBS antigens in their composition, pages 2992 and 2997 specifically identify GBS 80 and GBS 322 as the GBS proteins as two such GBS protein antigens, each having the identical amino acid sequences as Applicants’ polypeptides. The Office has indeed established a *prima facie* case of obviousness. The rejection stands.

New Rejection(s) Necessitated by Applicants’ Amendment

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

29) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

30) Claim 4 is rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 4, as amended, replaces the previously recited Markush language encompassing said GBS polypeptide antigen species with the non-Markush language ‘which further comprises GBS 91 and GNS 691 ...’. Accordingly, instead of having one Markush combination species as recited previously, the composition of the amended claim 4 now is required to comprise the at least two ‘isolated’ GBS polypeptide antigens from claim 1, i.e., GBS 80 and

GBS 322 **plus all** of elements (1) through (17) recited in claim 4. Note that elements (1) through (17) recited in claim 4 are not required to be isolated. However, there is no descriptive support in the as-filed specification for such a composition that comprises a specific combination of isolated GBS 80 and GBS 322 and non-isolated elements (1) through (17) along with an isolated GBS saccharide antigen from GBS serotype Ia, as claimed currently. Applicants have not pointed to specific parts of the specification that provide support for the composition now claimed in claim 4. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or remove the new matter from the claims. Applicants should specifically point out the support for any amendment made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

31) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

32) Claims 1, 3, 4, 7-15 and 18-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is indefinite because it lacks proper antecedent basis in the limitation: ‘GBS 80’ (see line 8) and ‘GBS 322’ (see line 32). For proper antecedence, it is suggested that Applicants replace the above-identified limitations with the limitations --the GBS 80-- and --the GBS 322-- respectively.

(b) Analogous rejection and criticism apply to claim 3 with regard to the limitation ‘GBS 80’ in lines 2 and 3.

(c) Analogous rejection and criticism apply to claim 8 with regard to the limitations ‘GBS 80’ and ‘GBS691’ in line 2 of the claim.

(d) Analogous rejection and criticism apply to claim 9 with regard to the limitation 'GBS 80' in line 2 of the claim.

(e) Analogous rejection and criticism apply to claim 18 with regard to the limitations 'GBS 80' and 'GBS 322' in lines 2 and 3 of the claim.

(f) Claim 19 is indefinite because it lacks proper antecedent basis in the limitation: 'a GBS Ia saccharide antigen'. Claim 19 depends indirectly from claim 1 which already includes an isolated GBS saccharide antigen from GBS serotype Ia. Is 'a GBS Ia saccharide antigen' recited in claim 19 a non-isolated GBS Ia saccharide antigen different from the one recited in the base claim?

(g) Claim 3 is indefinite, confusing and has improper antecedence in the limitation: 'the immunogenic fragment of GBS 80'. Claim 3 depends from claim 1, which includes the plural limitation of 'immunogenic fragments of GBS 80'.

(h) Claims 1 and 4 are indefinite and confusing in the limitations: 'GBS 691 ... of SEQ ID NO: 34' and 'GBS 691 set forth as SEQ ID NO: 36' respectively. See last two lines of each of the claims. It is unclear how the same GBS 691 can have SEQ ID NO: 34 and SEQ ID NO: 36.

(i) Claim 7 is indefinite and confusing in the limitation: 'a combination of at least three GBS polypeptide antigens'. Claim 7 depends from claim 1, which includes the limitation: 'at least two isolated GBS polypeptide antigens'. Are the 'at least three GBS polypeptide antigens' recited in claim 7 different from or in addition to the 'isolated' GBS polypeptide antigens recited in the base claim 1?

(j) Claims 1 and 8 are inconsistent in the limitations: 'GBS 691' and 'GBS691' respectively. Are these two different elements?

(k) Claims 3, 4, 7-15 and 18-23, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

33) Claims 1, 3, 4, 7-15 and 18-23 stand rejected.

34) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

35) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments and papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

36) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

37) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2010